

make said IGF-I or analogue thereof soluble at a concentration of about 12 mg/ml or greater when said composition is at a temperature of about 4°C.

F 2 3 31. (Twice amended) The composition of claim 29, wherein said solubilizing compound is selected from the group consisting of arginine, N-acetyl-arginine, a dipeptide containing arginine, and a tripeptide containing arginine, wherein said dipeptide or said tripeptide increases solubility of said IGF-I or analogue thereof at a pH of about pH 5.5 or greater.

C/O 3 18 46. (Twice amended) A composition comprising:  
(a) biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, wherein said IGF-I or analogue thereof is present at a concentration of about 12 mg/ml or greater when said composition is at a temperature of about 4°C;

(b) a solubilizing compound selected from the group consisting of arginine, N-acetyl-arginine, a dipeptide containing arginine, a tripeptide containing arginine, and guanidine hydrochloride, wherein said dipeptide or said tripeptide increases solubility of said IGF-I or analogue thereof at a pH of about pH 5.5 or greater; and

(c) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.

21 85. (Amended) A composition having a pH of about pH 5.5 or greater, wherein said composition comprises:

(a) biologically active human insulin-like growth factor-1 (IGF-I), wherein said IGF-I is present at a concentration of about 12 mg/ml or greater when said composition is at a temperature of about 4°C; and

(b) a solubilizing compound comprising a guanidinium group, wherein said solubilizing compound is present in said composition in an amount sufficient to

make said IGF-I soluble at a concentration of about 12 mg/ml or greater when said composition is at a temperature of about 4°C.

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99. (Amended) A composition comprising:

- (a) biologically active human insulin-like growth factor-1 (IGF-I), wherein said IGF-I is present at a concentration of about 12 mg/ml or greater when said composition is at a temperature of about 4°C;
- (b) a solubilizing compound selected from the group consisting of arginine and guanidine hydrochloride; and
- (c) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.

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101. (Amended) A composition having a pH of about pH 5.5 or greater, wherein said composition comprises:

- (a) biologically active human insulin-like growth factor-1 (IGF-I), wherein said IGF-I is present at a concentration of about 12 mg/ml or greater when said composition is at a temperature of about 4°C; and
- (b) arginine in an amount sufficient to make said IGF-I soluble at a concentration of about 12 mg/ml or greater when said composition is at a temperature of about 4°C.

#### REMARKS

Claims 29, 31, 46, 85, 99, and 101 have been amended to replace the phrase "at least about . . ." with the phrase "about . . . or greater" for the reasons noted below. Support for recitation of this phrase resides throughout the specification, in the phrase "at least about . . ." as presented in the original claims, and in claims 31 and 46-48 as originally filed. No new matter is added by way of claim amendment.

Applicants wish to thank Examiner Chih-Min Kam for the helpful telephone interviews of November 8 and November 25, 2002. Her suggestions have been taken into consideration in the preparation of this amendment.

Claims 29-48 and 85-130 are now pending in the application. Applicants present these claim amendments to expedite prosecution, and in no way are these amendments intended to narrow the scope of these pending claims. Reconsideration of the claims in view of these amendments is respectfully requested. The Examiner's remarks in the Office Action are addressed below in the order set forth therein.

The Rejections of the Claims Under 35 USC §112, Second Paragraph, Should Be Withdrawn

Claims 29-48 and 85-112 stand rejected under 35 USC §112, second paragraph, as being indefinite. Specifically, the Office Action states that claims 29-48 and 85-112 are indefinite because of the use of the terms "at least about pH 5.5" and "at least about 12 mg/ml." This rejection is respectfully traversed as applied to the amended claims.

Responsive to the Examiner's indication in a telephone interview of November 8, 2002, and subsequently in a telephone interview of November 25, 2002, that claim amendments to change the phrase "at least about . . ." to "about . . . or greater" would resolve this indefiniteness rejection, Applicants respectfully request that the Examiner enter the claim amendments presented herein. These claim amendments were not presented earlier as Applicants were and still are of the opinion that the claims reciting the phrase "at least about . . ." are definite for the reasons made of record in the responses filed February 8, 2002, and September 3, 2002.

Applicants respectfully submit that the scope of these amended claims is also definite, and as such, this rejection of the claims should be withdrawn.

In the Office Actions mailed October 9, 2001 (Paper 22), and May 31, 2002 (Paper 25), claims 35-39, 88-92, and 102-106 were rejected for recitation of the phrase "from about . . . to about . . .". As Applicants have previously made of record, the phrase "from about . . . to about . . ." is essentially the same as the other phrases previously suggested by the Examiner as being definite, i.e., "between . . . to . . ." or "about . . . to about . . ." (see the Office Action mailed October 9, 2001; Paper 22).

In the Amendment and Response filed September 3, 2002, Applicants requested that these claims be amended to recite the phrase "of about . . . to about . . ." in place of the phrase "from about . . . to about . . .". However, the amendments presented in that Amendment and Response were denied entry as the response as a whole was not considered to place the application in condition for allowance.

The Examiner has now indicated in the telephone interviews of November 8, 2002, and November 25, 2002, that this indefiniteness rejection will be reconsidered upon presentation of this Supplemental Amendment. Accordingly, it is believed that use of the phrase "from about . . . to about . . ." is acceptable and that claims 35-39, 88-92, and 102-106 are definite. In view of this, Applicants respectfully request the Examiner to withdraw this rejection.

#### CONCLUSION

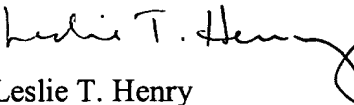
In view of the above amendments and remarks, Applicants submit that the rejection of the claims under 35 USC §112, second paragraph, is overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

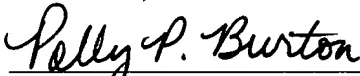
It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR

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§1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

  
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<b>CUSTOMER NO. 00826</b> <b>ALSTON &amp; BIRD LLP</b> Bank of America Plaza 101 South Tryon Street, Suite 4000 Charlotte, NC 28280-4000 Tel Raleigh Office (919) 862-2200 Fax Raleigh Office (919) 862-2260	<b>CERTIFICATE OF MAILING</b>  I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: <b>BOX AF</b> , Commissioner for Patents, Washington, DC 20231, on November 27, 2002.   Polly P. Burton
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